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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------|------------------|
| 10/630,374 | 07/30/2003 | Jean-Pierre Salaun | 16721-0210 (42528-288279) | 8956 |
| 20306 | 7590 | 10/20/2005 | EXAMINER | |
| MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606 | | | GEMBEH, SHIRLEY V | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1614 | |

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/630,374 | SALAUN ET AL. | |
| | Examiner | Art Unit | |
| | Shirley V. Gembeh | 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8, 11 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8, 11, 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1614

DETAILED ACTION

Receipt is acknowledged of amendment filed 09/08/2005. Claims 1-5, 9-10, 12-13 are cancelled; therefore claims 6-8, 11 and 19-22 are pending. Applicant's request for reconsideration of the rejection of the claims in the last office action is being considered.

Claim Rejections - 35 USC § 102

The rejection of claims 4 and 9 under USC § 102 (b) is moot in view of the cancellation of claims 4 and 9.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yani et al., US 5,696,166 in view of Wollard. Prostaglandins 1989, Vol. 38 (4) pages 465-471 and Herbertsson et al., J. of Lipid Research, 1998 Vol 39, pages 237-244 for the reasons stated in the prior office action.

1. Yani teaches 12-hydroxy-5,8,14-(Z)-10-(E)-eicosatetraenoic acid (12-HETE) composition column 4 line 1-55, in an effective amount at column 5 line 47-49 as in claim 5, wherein the composition is administered in the form of gel column 5 lines 27 as disclosed in claims 6 and 11, where the 12-HETE comprises of 12(R) or (S)-HETE column 6 line 50, as in claim 7, 8, 12 and 13. Yani also teaches a pharmaceutical

Art Unit: 1614

composition that corrects/restores an organic function in humans (example- eye disorder) comprising an effective amount of 12-HETE column 5 lines 7+.

Yani however did not per se teach of inhibition of a fibroblast to an adipocyte, but since 12-HETE is an arachidonic metabolite, one of ordinary skill in the art would have expected differentiation of a fibroblast to occur anyway because arachidonic acids metabolites inhibits adipocytes productions which illicit inflammatory response via prostaglandins synthesis.

The response of September 8, 2005 page 5 first paragraph, presents argument of: that PG52 is one of the arachidonic acid metabolites that does not inhibit but accelerates differentiation of fibroblast into adipocytes. The argument is unpersuasive because: although as mentioned by applicant that PG52 is one of the arachidonic acid metabolites, the claims (eg 5 and 10) presented clearly states a method of inhibiting differentiation of a fibroblast to an adipocyte comprising administering to a human or an animal an effective amount of a composition comprising at least one of 12-HETE or 11,12-EET, nowhere in the references of Yani and Wollard was mentioned PG52 as argued by applicant.

The compound 12-HETE used by applicant is the same used by Yani and Wollard. Contrary to applicants assertion administering the compound/drug would render the same result regardless i.e. inhibit fibroblast to adipocyte, thus inhibition is to the adipocyte.

Thus the argument is not persuasive.

2. Herbertsson et al., teach (on page 240, right hand side column underlined), of

Art Unit: 1614

detection of 12(S)-HETE to other cells, and in the discussion section on page 242 teach the expression in pre-adipocytes which appears to inhibit differentiation to adipocytes as in claim 10.

The response of September 8, 2005 page second paragraph, presents argument

"3T3-L1 preadipocytes bound approximately the same amount of 12(S)-HETE as Lewis lung carcinoma cells. When these cells had been differentiated to adipocytes, the binding capacity was reduced about six times."

of: 1.

Herbertsson

used 5 different cell lines, 3T3-L1 binds approximately the same amount of 12(S)-HETE as Lewis lung indicating that once the cells are differentiated to adipocytes the binding capability was reduced, these cells were however used as a negative control as they do not produce 12(S)-HETE, further in the reference (page 240 left column Herbertsson showed reduced binding with 12-HETE, also at page 242 right hand column, second paragraph, states that TNF-induced c-fos expression which appears to be dependent on formation of HETEs prevented differentiation to adipocytes.

2. Contrary to applicants' argument on page 6 bottom half, that the differentiation of the 3T3-L1 was not inhibited is not founded, at page 242, right hand column, it clearly states the observed decrease in the amount of 12(S)-HETE binding complex in differentiated 3T3-L1 cell.

Art Unit: 1614

Thus the argument is not persuasive.

Claims 6-8 and 11 remain rejected and newly added claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herbertsson et al., J. of Lipid Research, 1998 Vol 39, pages 237-244 in view of Yani et al., US 5,696,166.

Herbertsson teaches current claim 19 a method of inhibiting differentiation of fibroblast to adipocyte at page 242 (right hand col. second paragraph), wherein the metabolite is 12(S) current claim 22 (see abstract).

Yani teaches current claim 6, wherein the composition of 12-HETE is administered in the form of gel at col. 5 line 27, wherein one 12-HETE comprises of 12 (R) (S) current claims 7 and 8 at col. 6 line 50.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer 12-HETE compositions- an arachidonic metabolite to treat human neutrophils and for cell survival. These compounds are known in the art to bind to human leukemia cell and murine pre-adipocytes by blocking specific 12S or 12R receptors.

One of ordinary skill in the art would have been motivated to combined the teachings of Herbertsson with that of Yani, used either 12 (S) or 12(R) to inhibit differentiation of fibroblast to adipocyte as both enantiomers are metabolites of the arachidonic acid and has both been used in the prior art, therefore would have expected successful result in doing so.

Thus claims are prima facie obvious over the cited prior art.

Art Unit: 1614

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 - 5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVS

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10/11/05


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